

Remarks

Claims 50-53 and 55-59 remain pending in the application. No new matter has been added by this amendment.

Claim Rejections – 35 U.S.C. § 103(a) – Lai et al

Claims 50-53 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz in combination with Singer et al.

It is submitted that the Examiner's statement that "Lai et al teach a method of cellular disruption as claimed except for the specific concentration of SDS (column 5, line 36 to column 19, line 67)" is incorrect. Lai et al does not disclose the method as claimed.

Lai et al recites a comparative experiment to test the relative photodynamic activity of preparations and materials. Column 15, lines 46-48. The experiment is an in vitro test carried out in five aqueous solutions. Column 16, lines 1 – 6. One of the solutions contains SDS at a concentration of 0.07 Molar. A concentration of 0.07M equates to approximately 2.02%, or approximately 25 times greater than the highest concentration of SDS of the present claims. The relative photodynamic activity of the solutions is examined as measured by a recording oxygen electrode system. No cells or cellular organisms are present in this in vitro examination. There is no teaching or suggestion to use the solution containing SDS in an in vivo context in a method as claimed.

Lai et al. does not disclose, teach or suggest the claimed step of using SDS to disorient a cell membrane so that the cell membrane no longer functions as an effective osmotic barrier and then passing a photosensitive material through a disoriented cell membrane and into a cell interior.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The combination of the Lai and Singer would fail to teach or suggest each of the following steps:

identifying an area of cell activity;

applying a concentration including a combination of a surfactant and a photosensitizing agent to the area of cell activity, said surfactant disorienting a cell membrane so that said membrane no longer functions as an effective osmotic barrier;

passing the photosensitive agent through a disoriented cell membrane and into a cell interior;
and

applying light to the photosensitive material within the cell interior, said light having a light wavelength, light dosage and a light dosage rate to cause photodynamic cellular disruption, wherein the surfactant is SDS provided in a solution having an SDS concentration range of between 0.003 % to 0.01%.

A proposed modification of Lai et al. to lower the concentrations of SDS to the presently claimed ranges would not be obvious as such a modification would render the prior art invention unsatisfactory for its intended purpose, i.e. to improve the solubility of poorly soluble porphyrin (surfactant concentrations above CMC are necessary to form micellar complexes and improve solubility). See, M.P.E.P §2143.01, citing *In re Gordon*, 733 F2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, any proposed modification of Lai et al to lower the concentration of SDS to the presently claimed ranges would not be obvious as such a modification would change the principle of operation of the prior art invention being modified. See, M.P.E.P §2143.01, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The presently claimed concentration range

of SDS would not be an obvious variation of the teachings of Lai et al., as such modifications would render the prior art invention unsatisfactory for its intended purpose, i.e., to improve the solubility of poorly soluble porphyrin. Further, any proposed modification of Lai et al. to lower the concentration of SDS to the presently claimed ranges would not be obvious as such modification would change the principle of operation of the prior art invention being modified.

Claim Rejection: 35 U.S.C. §103 -Swartz Asculai Singer Williams

Claims 55 and 57-59 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz et al in combination with Asculai et al, Singer et al, and Williams et al.

No combination of these references would teach or suggest the claim limitation of a specific concentration range of SDS. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Additionally, there is no motivation to combine Asculai with Williams et al. Asculai teaches the use of a nonionic surfactant to treat viruses:

"By the present invention a method of inactivating herpes simplex viruses is provided. The viruses are inactivated by treating the infected area with a nonionic surface active agent. Nonionic surface active agents, in contrast to cationic, anionic and ampholytic surface active agents, contain no ionizable groups and have no surface charge." Column 1, lines 26-32.

SDS is an anionic surfactant having a surface charge. SDS can be used to solubilize fats and oils, lower the surface tension of aqueous solutions, or form microemulsions. Singer p. 96.

Asculai teaches away from the use of SDS by indicating that only a nonionic surfactant be utilized to inactivate viruses. There is no suggestion or motivation to modify Asculai in order to exchange a nonionic surfactant with SDS, as the proposed modification would render the prior art invention unsatisfactory for its intended purposes. If the proposed modification would

render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See, M.P.E.P §2143.01, citing *In re Gordon*, 733 F2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

It is improper to combine Asculai and Singer as the references teach away from their combination. See, M.P.E.P §2145.

Reconsideration of these rejections is requested.

Claim Rejection: 35 U.S.C. §103 –Swartz Asculai Singer Williams Lai

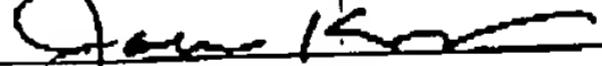
Claim 56 was rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz et al in combination with Asculai et al, Singer et al, and Williams et al as applied to claims 55 and 57-59 above, and further in view of Lai et al.

For the reasons identified above with reference to claims 55 and 57-59, it is submitted that this rejection of claim 56 is improper. Reconsideration of this rejection is requested.

Please direct any questions regarding this application to John Klos at (612) 321-2806.

Respectfully submitted,
Merrill A. Biel, and Advanced
Photodynamic Technologies, Inc. by their
attorneys

Dated: September 8, 2003

By: 
John F. Klos, Esq.
Registration No. 37,162
Fulbright & Jaworski L.L.P.
225 South Sixth Street, #4850
Minneapolis, MN 55402-4320
Telephone: (612) 321-2806